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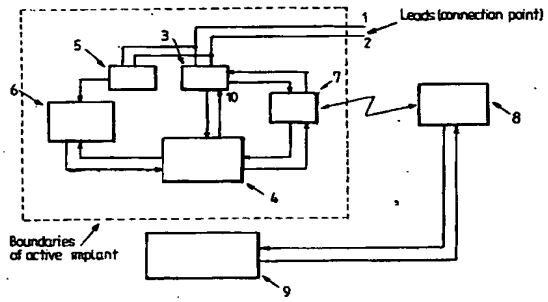
(54) Rate responsive pacemaker

(57) The invention relates to an active cardiac implant connectable to implantable electrode means adapted for in vivo delivery of stimulation pulses to a heart in dependence of the workload of a patient, which implant comprisis monitoring means (4) for registering of IEGM-signal present on input terminals (1,2) from one or more of said electrode means; pulse generator means (3), connectable to said electrode means, adapted for generating and emitting stimulation pulses with a variable stimulation interval between successive stimulation pulses, said pulse generator having at least one control input (10); a classifying device (6) adapted for classification of a predetermined number of IEGM-signals registered during predetermined time intervals at predetermined points of time according to a predetermined classification stored into said device, said classification being related to preregistered waveforms of measured IEGM signals; a control unit (4) having control means adapted to supply a control signal to said one input (10) of said pulse generator in dependence of the classification of each of said registered IEGM signals; and said control signal being adapted to cause the pulse generator to adjust the stimulation rate in dependence of said each of said registered IEGMsignals.

Fig.5



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Description

Background of the Invention

1. Field of the Invention

The present invention relates to a rate-responsive pacemaker of the type having at least one pulse generator which generates and emits stimulation pulses with a variable stimulation interval, a control device which controls the pulse generator's stimulation intervals and a method for rate-regulation of the stimulation pulses.

General

The problem connected with most pacemakers is a relative lack of a physiological rate control. A rather large group of physically active patients would benefit from improvements in this area. In addition to for instance impedance measurements for relating oxygen demand of the patient to the workload several other solutions have been tested but they still do not deliver accurate cardiac rate regulation. Other such methods include the use of sensors measuring different physical parameters such as acceleration or blood pressure. The use of sensors of different kinds of course complicates the heart stimulators leading to increased manufacturing costs and reduced reliability as the possibility of component failure in anyone of the components increases proportionally to the number of components.

Summary of the Invention

An object of the invention is to provide a rate-responsive heart stimulator which effectively optimizes cardiac output on the bases of measurable activities in the heart.

Another object is to provide a heart stimulator for relating these same measurable activities in the heart to the situation of the patient, i.e. the oxygen demand of the body of the patient.

Such a heart stimulator is achieved in accordance with the principles of the present invention.

When blood in the heart has been ejected in a normal cardiac cycle and the muscle tissue relaxes for refilling, the influx of blood into the heart is governed by blood pressure in the vascular system. At the beginning of diastole the blood flows rapidly into the heart. The flow ultimately ceases when the heart is full of blood, i.e. when the pressure in the heart and in the vascular system equalize. In addition, the influx of blood into the heart depends on the physical and mental condition of the person in whom the stimulation device is implanted. At rest the influx of blood into a patients's heart is slower at the beginning of diastole than during physical exercise or stress.

When applying a workload to a patient there is a need for extra oxygen, which need can be satisfied by e g an increase in the heart rate such that the flow of blood through the heart increases. An other method is to increase the stroke volume. Both these ways will invariably result in physiological changes in the heart muscle.

It has now surprisingly been found that when registering IEGMs (Intracardiac electrograms) systematic changes in the IEGM waveform morphology appear as a workload is applied to a patient. It has also surprisingly been found that these systematic changes in the IEGM can be used for estimating the workload of the specific patient.

We have found that when a constant stimulation frequency is upheld and the level of physical exercise (i.e. oxygen demand of peripheral tissue) is varied, systematic changes in IEGM wave-form morphology are observed.

It has now surprisingly been found that these waveform morphology changes can be used to rate regulate a heart-stimulator in a way which does not make necessary the use of any extra intra- and/or extracardiac sensor or electrodes. Such extra devices invariably creates a demand for the implanted device to supply extra power which means that the absence of such extra sensors or electrodes means that a requirement for low power consumption is more easily fulfilled than has been accomplished with earlier methods. Such extra electrodes and/or sensors may also cause electrical interference with the necessary registering of the heart activity. Thus it has been shown that according to the invention the morphology changes can be used to control a stimulator which does not make use of extra intracardiac or extra-cardiac sensors.

The invention will be further described below with reference to the drawings.

DESCRIPTION OF THE DRAWINGS

FIG. 1 Diagram showing averaged IEGM measurements from a bipolar lead in the ventricle, the patient being put under different workloads and being paced with a mean rate of 70 bpm.

FIG. 2 Diagram showing averaged IEGM measurements from a unipolar lead in the ventricle. The patient being paced at a rate of 70 bpm.

FIG. 3 A schematic drawing of one possible implementation of a neural network or signal processing system.

FIG. 4 An example of a wavetable in accordance with the invention.

FIG. 5 Schematic block diagram of a embodiment of an implantable heart stimulator according to the invention.

FIG. 6 An example of a neural chip based classifier implementation.

FIG: 7 An example of a microcontroller based classifier implementation.

Figure 1 shows averaged IEGM measurements for different loads formed from 20 consecutive heart beats

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recorded from a bipolar lead. The lead was placed in the ventricle and both the sampling and the stimulation was performed via the same lead. The patient with a recently implanted pacemaker, was paced at 70 bpm throughout the recording of the IEGMs. The recording of the IEGMs was started at the stimulation pulse and the sampling rate was 100 samples/s making each sample correspond to 10 ms, the X-axis is in ms and the Y-axis corresponds to the polarity and amplitude of the sampled points. The curves in the diagram correspond to the different workloads applied: rest, 30 watts, 50 watts and 75 watts. The most interesting segments of the IEGM:s occur between 175 ms to 425 ms after the time of the stimulation pulse.

The implant according to the invention may use all of the registered IEGM or segments of the IEGM may be chosen for use with the implant according to the invention. This means that the measured IEGMs must be related to a predetermined point of time, which in this case could be the stimulation pulse.

If in this case the patient had had an active implant which would provide for the possibility of a spontaneous heart beat and only would give a stimulation pulse in the absence of a spontanous beat this stimulation pulse would then be the predetermined point of time for the actual measurement.

Figure 2 shows averaged IEGM measurements for different loads formed taken 20 consecutive heart beats recorded from a unipolar lead. The lead was placed in the ventricle and both the sampling and the stimulation was performed via the same lead. The patient with a chronic implanted pacemaker, was paced at 70 bpm throughout the recording of the IEGMs. Chronic means that the electrodes and the leads have been implanted for some time as compared with acute. The sampling rate is 100 samples/s making each sample correspond to 10 ms, X-axis is graduated in ms and the Y-axis corresponds to the polarity and amplitude of the sampled points. The curves in the diagram correspond to the different workloads applied: rest, 30 watts, 50 watts, 75 watts and 100 watts. The most interresting segment seems to be about 100 ms to 300 ms from the stimulation pulse.

In the figures the total time window is 500 ms which corresponds to 51 samples. At the paced rate of 70 bpm the time between each heart stroke is 860 ms. During the 360 ms not shown in the graphs in the figures the registered signal is essentially iso-electric (0 V) and thus not of interest for showing changes under different workloads.

As can be seen from the curve in figure 1 there are registerable changes between the curves related to different loads. It is to be noted that IEGMs from different leads and different persons will always look different. In the same person the curve registered will also depend on the exact location of the tip of the lead. There is of course a relation to the appearance of, the surface-ECG but the appearance of the IEGM is different because the signals are directly measured in the heart itself and not on the surface of the body.

The same type of changes can be seen in the graph in fig 2 where the most important changes in amplitude seem to occur in the area around 150 to 260 ms. The type of lead and the exact location of the electrodes of the lead accounts for the general appearance of the IEGM registered. This is purely a methodology question depending on how the leads are connected when measuring.

Thus it can be concluded that the area where the changes in the waveform are most prominent corresponds to the latter part of the QRS-complex and the T-wave.

According to the present invention it has been shown that these noted changes may be used as the qualitative basis for the rate-responsive heart stimulation. The differences in between the different load cases are not very big but are still quite easily detected by using a form of a neural network.

The principle behind this is to provide a device able to classify registered IEGMs as waveforms, i.e. the registered IEGMs such as shown in FIG. 1 and FIG. 2 above. These classified waveforms are then put into a wavetable.

A wavetable, or waveform table is an organised storage of waveforms. The origin of the term comes from sound synthesis technology where digitised waveforms are stored in memory as a wavetable. The waveforms according to this invention are not easily retrievable since their characteristics are coded in the synaptic weights of a neural network. However, the abstract concept of a wavetable is useful for explaining the present invention.

The classification of the registered waveforms is accomplished using e.g a neural network. In order to do this it is preferred that the individual patient performs a series of workloads e.g. on an ergometric cycle. For each workload a range of pacing rates are scanned, i.e. the patient goes through a number of tests under the same load but with the pacing rate set differently for each run. For each rate the waveform is recorded by the device. A wave table may be stored relating pacing rate and workload and morphology for the specific patient.

Such a wavetable is shown in figure 4. In the table waveforms corresponding to different heart rates and different workloads for a patient is shown and the waveform presenting the most favourable pacing rate for the actual workload is marked by a dashed box. Thus it may be inferred from this wavetable that at rest the patient should preferably be under a stimulation rate of 70 bpm and when under a workload of 100 watts should preferably be under a stimulation rate of 120 bpm.

In order to realise these waveform patterns a neural network may be utilized. Such a device has to undergo a training procedure to be able to recognize and categorize different waveforms.

The neural network is applied for performing a classification of the waveforms, as a part of the monitoring of the pacing, during the use of the heart stimulator. In

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one instance 51 consecutive samples been used as an input to the neural network for training a multilayer perceptron with backpropagation. The recorded IEGMs were digitized and stored in a computer then a IEGM morphology analysis and the neural network simulations were made. Using this relatively crude method correct classifications could be made on a beat to beat basis.

Since the IEGM waveform changes with pacing rate the neural network has to be trained with segments of waveforms data from a number of heartbeat intervals from the patient and also several different pacing rates. The network may e g be trained on data from a chosen number of corresponding segments and heart rates, the segments preferably being those segments showing the biggest variations between different workloads.

Training the neural network is computationally extensive and may therefore be performed in a separate external unit, where power consumption is not a problem. The parameters of the trained network are then transferred to the pacemaker, which only performs the classification. Since classification requires relatively few operations it can be performed in an implantable device with low power consumption

In this context a short description of a neural network, a multilayer feedforward network, is presented in connection with figure 3.

The use of neural networks for detection and classification of intracardiac electrograms primarily for detecting arrythmias are known from EP-0,465,241 and US-5,280,792.

A neural network generally has the option of receiving several input signals and generating therefrom one or more output signals. Each input signal is processed and combined with the other weighted input signals. The combinations of the signals are further processed in order to produce one or more output signals. The processing of the signals contains multiplication, addition and non-linear operations. A neural network may have different structures. This structure must first be decided. The neural network then has a number of unknown parameters (w_{nn}, b_n, weights and biases). A characteristic for the neural network is that it must learn how to adjust these parameters.

The input signals shown are in the shown example are S1, S2, S3 and S4. Each input signal is then multiplied by a certain weight (w_{11} to w_{4k}). For every input signal there are as many weights as there are summing junctions. In figure 3 there are k summing junctions. In the summing junction all weighted signals and a bias signal are added. The bias signal is a constant necessary for the functioning of the neural network.

The output signal from the summing junctions is then passed through a transfer function, denoted "Φ". Very often this transfer function is a non-linear function, like the sigmoid function. In the very same way as the input signals are processed the output signals from the transfer function blocks are now handled. Here there are new weights, v_{11} to v_{km}, b_1 to b_m. In this figure only one single output, Sout is shown. The transfer function is denoted "F". Normally this last transfer function is a linear function.

The neural network used in the implant according to the invention can be somewhat different from the above example but the operation of the network will be the same.

The learning action is performed on representative input signals which are fed into the neural network in order to produce an output signal or pattern, which will be compared with a reference signal or pattern. The learning procedure is performed by repeatedly feeding these input signals to the neural network and adjusting each parameter so that finally the output signal or pattern from the neural network resembles the reference signal or pattern. The neural network is now adjusted. New input signals will then produce output signals or patterns, which will be similar to the signals or pattern that the process, which the neural network is simulating, will produce.

Neural networks are today relatively well established tools for pattern classification tasks. Several different network types and learning algorithms may be used for solving this particular problem. The invention has been tested with a multilayer feedforward network trained by using the backpropagation algorithm. There are also statistical methods equivalent to neural networks that do basically the same job. These methods may however be viewed as distinctly different from neural networks. Finally, a neural network can be converted to fuzzy logic. Fuzzy logic may be more favourable than neural networks for hardware implementation.

When the pacemaker is in use the device continuously monitors the heart beats. This also includes monitoring of the waveforms. If the waveform detected by the device is not the optimal, the pacing rate has to be changed either up or down, depending on the characteristics of the waveform. This procedure will be repeated until the device finds an optimal waveform match.

The produced waveform table (wavetable) after being produced is stored in the implantable device and may be fine tuned by the patient or by a doctor.

Description of preferred embodiments

Figure 5 shows an embodiment of the device according to the invention in the form of an active implant. The units within the dashed line are units comprised within the implant. Connected to the input terminals 1 and 2 of a unipolar or bipolar lead is a pulse generator 3, shown as a functional block. This block comprises contain circuitry for generating the heart stimulation pulses. The block also contains circuitry for interfacing with the control unit 4. The control unit 4 has a overriding function in establishing the stimulation rate.

In another embodiment the control functions could just as well be placed in another unit, since this is only a matter of organizing the functions.

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The device also comprises a IEGM amplifier 5 having means for amplification and filtering of the IEGM signal The amplifier 5 is connected to the input terminals for receiving IEGM-signals from connectable implanted leads and for amplifying the IEGM signals. The amplified signal are thereafter sent to the next block in the implantable device.

The next block comprises a classifier 6, which is the heart of the described invention. Its main function is to classify the registered IEGMs into different morphological groups (wave groups). This is the key to the described rate regulation method. The classifying function can be implemented in several different ways both as regards the underlying algorithms and the hardware used, as will be discussed below in connection with figures 6 and 7.

The control unit 4 interprets classification results from the classifier 6 and according to that interprets and sends rate regulating signals to a control input 10 on the pulse generator 3.

The control unit 4 also controls which set of weights is to be used by the classifier and handles the transfer of weights via telemetry. The wave table is coded as several sets of weights.

The active implant also comprises a telemetry unit 7 that allows for bi-directional transfer of data.

An external telemetry unit 8 is also shown which is connected to an extracorporeal device 9 in which the training process of the neural network may be performed. The device 9 receives IEGM data from the active implant and trains an external neural network on these data and sends the weights, those being the underlying data for the wave table, back to the implant, to be used by the classifier in conjunction with the control unit in regulating the stimulation rate to the appropriate one for the situation, that is to the workload the patient is subjected to.

In the future an external unit for training of the neural network may not be necessary in implementations of the active implant according to the invention since the power consumtion for sending bulk data via telemetry soon may be balanced by the power used for training carried out in the active implant.

The once established weights may for different reasons have to be changed by training the network with certain intervals i e in case of major changes in the status of the patient's heart. These changes must not necessarily be dependent on serious events occurring in the heart. Also due to the natural ageing of the heart one might suspect that the waveform table once registered may have to be changed. This means that a new set of weights should be established as functions of different workloads and rates. The correlation between workloads and the preferred pacing rate for the specific workload may have been changed.

However, this will be rather simple since new IEGMs may be registered using the already implanted leads and the signals may then be sent via the telemetry units to the extracorporeal device for establishing new classifier parameters.

Below follows a description of the tuning of the pacemaker to the individual patient.

1. After implantation of the device the patient performs a workload test on an ergometric cycle or a treadmill. At this stage the device will register IEGM-signals similar to those shown in figure 1 and 2. At each workload level several stimulation rates are used and IEGMs for a predetermined number of heart cycles are recorded for each heart rate and workload. The patient and/or the physician will decide on a stimulation rate as optimal for each level of exercise. In this way the wavetable (Figure 2) is established.

   The IEGM waveforms are sent via telemetry to the external device. The external device will use the data for training a neural network identical to the one used in the classifier. Some of the data will be used for validation of the network function.

   Once the neural network in the external device performs satisfactorily the internal weights will be sent back via telemetry to the weight memory of the classifier.

2. During normal operation the device continuously analyses the IEGM waveform morphology and control the heart stimulation rate thereafter.

Below an example of the normal behaviour of the active implant in use will be described using figure 4 as an illustration.

1. The patient is resting and the stimulation rate is 70 bpm, the IEGM waveform will have the appearance of #4. Since this is an optimal waveform no action is taken.

2. The patient starts to walk and the rate remains 70 bpm. The classifier output will indicate waveform #8, which is not optimal. In order to retain the optimal waveform the control unit will step up the rate to 90 bpm where waveform #7 will be indicated. Since #7 is an optimal waveform no further action is taken.

3. The patient goes back to rest but the rate remains 90 bpm. Waveform #3 will be indicated by the classifier. #3 is not an optimal waveform and the rate will be decreased by the control unit to 70 bpm.

The following is shown as an example of the procedure. IEGMs were recorded via temporary transcutaneous leads, connected to the implanted pacemaker system. The transcutaneous leads were attached to the pacemaker connector. After the experiment the temporary leads were disconnected by pulling them out. Both acute and chronic transveneous leads were used. All experiments were performed one day after the new

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implantation or replacement of the pacemaker. The experimental protocol consisted of a series of workload tests, typically at 30 to 75 watts. The recorded IEGMs were digitized and stored in a computer. The IEGM morphology analysis and the neural network simulations were made by using MATLAB® from MathWorks Inc.

A multilayer perceptron trained with backpropagation was used. The neural network was trained on data from 20 segments of the IEGMs at each workload level. The workload related morphological changes occured mainly in the part of the IEGM corresponding to the ST-segment of a surface-ECG.

Two examples of implementations of the neural network (classifier) are given below.

In figure 6 an implementation of the classifier, which is part of the active implant based on a neural chip is outlined. The measured analog IEGM signal 1 coming from the IEGM amplifier (not shown) in the active implant is fed into a analog delay line 20 where each segment of the delay line is connected via conductor 2 to a corresponding input of a feedforward network 21. The input signal is classified and the result of the classification is sent via conductor 3 to the logic unit 23 that passes it on via conductor 5 to the control unit (not shown) of the active implant (Figure 1). The weights of the network are stored in the weight memory 22, which has sufficient capacity for the storage of several sets of weights. The logic unit 23, connected to said control unit (not shown) and to the weight memory 22 selects which set of weights to use. The logic unit 23 receives information via conductor 4 on which set of weights to use from the control unit (not shown) of the active implant. The control unit bases its decision on the current heart stimulation rate forwarded from the pulse generator (not shown).

In figure 7 an implementation of the classifier based on a microcontroller is outlined. The analog in-IEGM signal is fed into an A/D port 42 of the microcontroller 40. The microcontroller 40 interacts with a memory for weight and data storage 41, which may be an integral part of the microcontroller 40. The microcontroller receives trigger pulses from the pulse generator (not shown) via a digital input/output port 43. Via another digital input/output port 44 the microcontroller 40 has a bidirectional communication with the controller unit (not shown) of the active implant.

The microcontroller has a neural network simulation program. The training is analogous with the earlier described method using an external computer. The segments of the registered IEGMs of interest in the individual patient is chosen and in the classifying procedure the choice of segments of the registered signals are synchronized using e g the stimulation pulse or some other welldefined event in the heart beat cycle. The software running on the microcontroller may be set up to form an average of 5 or 10 waveforms and classify the average waveform as belonging to a certain group.

Although the invention has been described with respect to particular embodiments, it is to be understood that these embodiments are merely illustrative to the application of the principles of the invention. Numerous modifications may be made therein and other arrangements may be devised without departing from the spirit and scope of the claims.

Claims

1. An active cardiac implant connectable to implantable electrode means adapted for in vivo delivery of stimulation pulses to a heart in dependence of the workload of a patient, said implant comprising:

   monitoring means (4) for registering of IEGM-signal present on input terminals (1,2) from one or more of said electrode means;
   pulse generator means (3), connectable to said electrode means, adapted for generating and emitting stimulation pulses with a variable stimulation interval between successive stimulation pulses, said pulse generator having at least one control input (10);
   a classifying device (6) adapted for classification of a predetermined number of IEGM-signals registered during predetermined time intervals at predetermined points of time according to a predetermined classification stored into said device, said classification being related to preregistered waveforms of measured IEGM signals representing different workloads of the patient;
   a control unit (4) having control means adapted to supply a control signal to said one input (10) of said pulse generator in dependence of the classification of each of said registered IEGM signals;
   said control signal being adapted to cause the pulse generator to adjust the stimulation rate in dependence of said each of said registered IEGMsignals.

2. An active implant according to claim 1, characterized in that it is adapted to classify IEGM waveforms in dependence of the workload of a patient by registering of a predetermined number of IEGM signals, each signal extending over at least one segment of one heart beat cycle, said classifying device adapted to process the predetermined number of IEGM signals or segments thereof by feeding said IEGM signals or segments thereof to a neural network, whereby an encoded form of said signals is formed using said neural network, said encoded form stored in a memory for use in classifying said further registered IEGM signals.

3. An active implant according to claim 1, characterized in that it is adapted to classify IEGM waveforms in dependence of the workload of a patient by registering of a predetermined number of IEGM sig-

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nals, each signal extending over at least one segment of one heart beat cycle, said classifying device adapted to feed the predetermined number of IEGM signals or segments thereof via telemetry to a processor in an external device comprising a neural network or set up to operate according to a system of fuzzy logic, wherein an encoded form of said signals is formed using said neural network or fuzzy logic, said encoded form sent to the active implant via telemetry to be stored in a memory for use in classifying said further registered IEGM signals.

4. An active implant according to any of the claims 1 or 3, characterized in that it is adapted to use in combination with said further registered IEGM signals, a preferred correlation of the workload and the pacing rate in a patient stored in a memory in the active implant, whereafter said implant is adapted to use said stored correlation for producing a control signal to be used for the regulation of the pacing rate of the implant

5. An active implant according to any of the claims 1-4 characterized in that said one segment of one heart beat cycle occurs between 175 ms to 425 ms after the generation of a stimulation pulse.

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Fig. 1

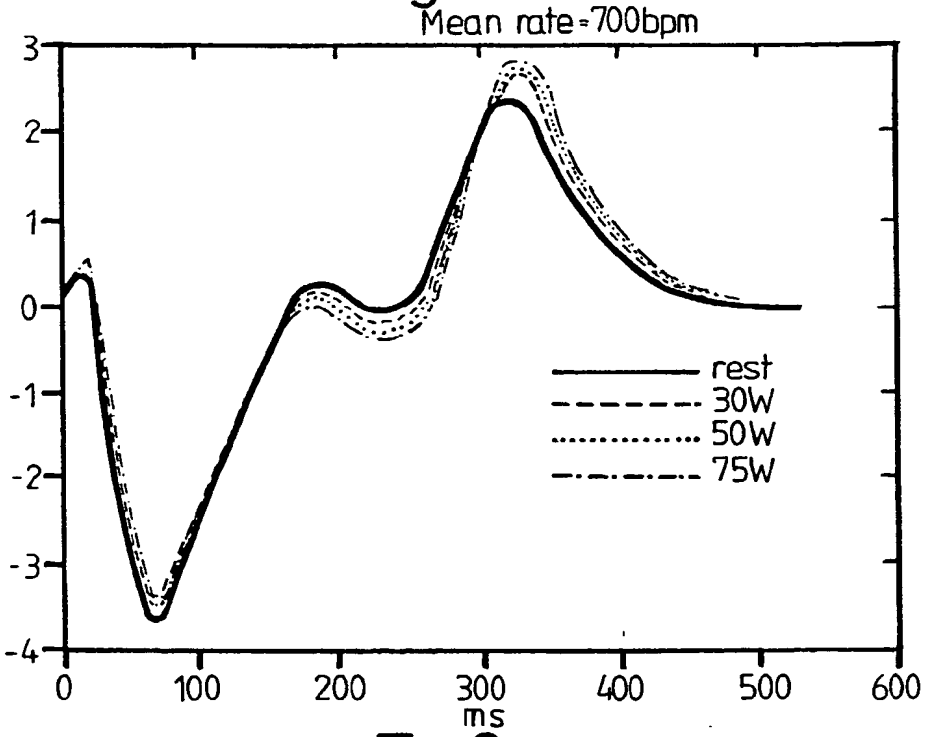
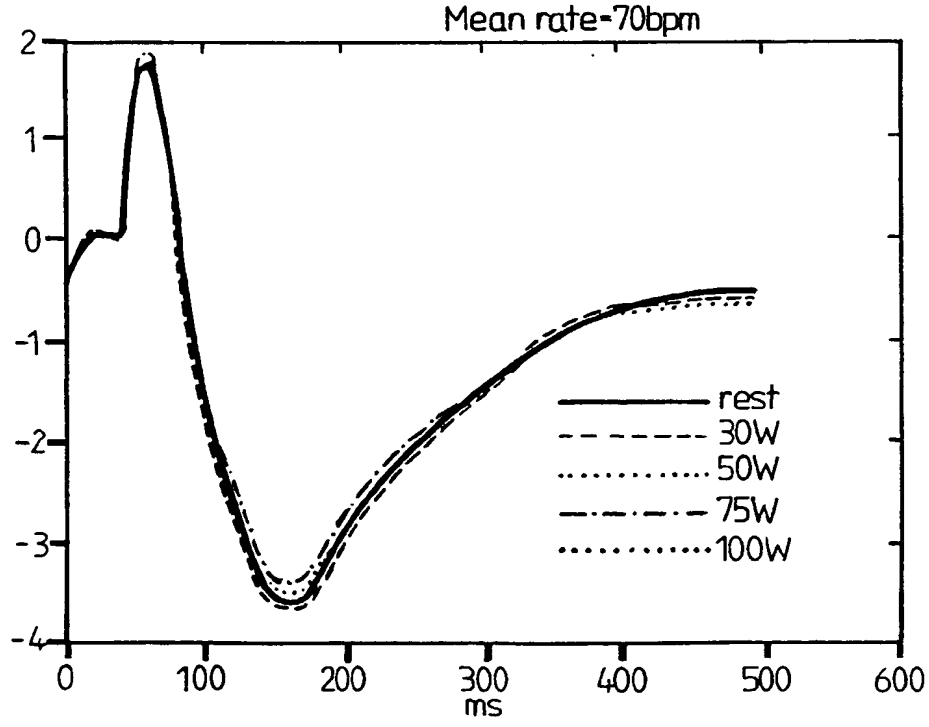


Fig.2



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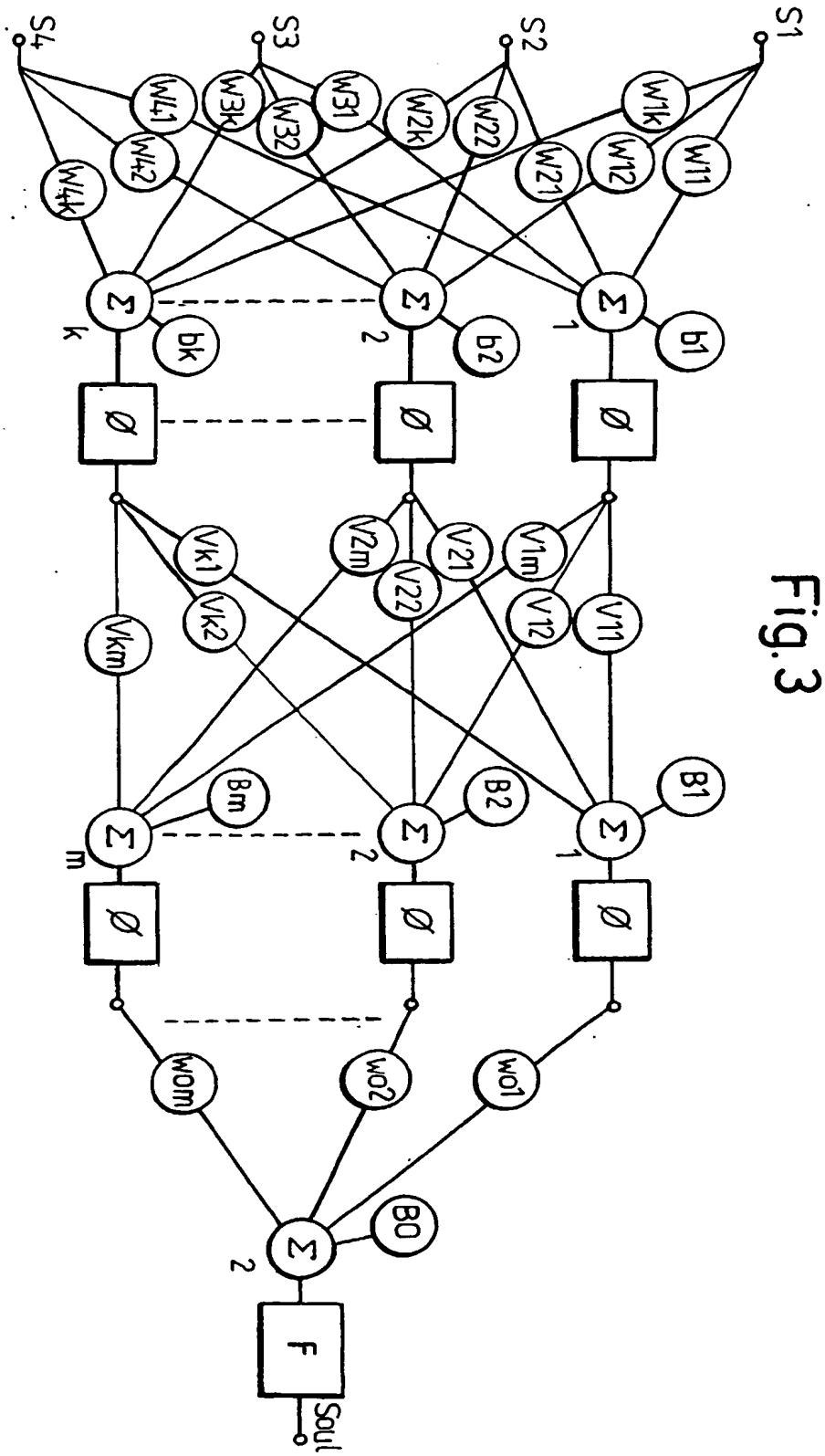

Fig.3

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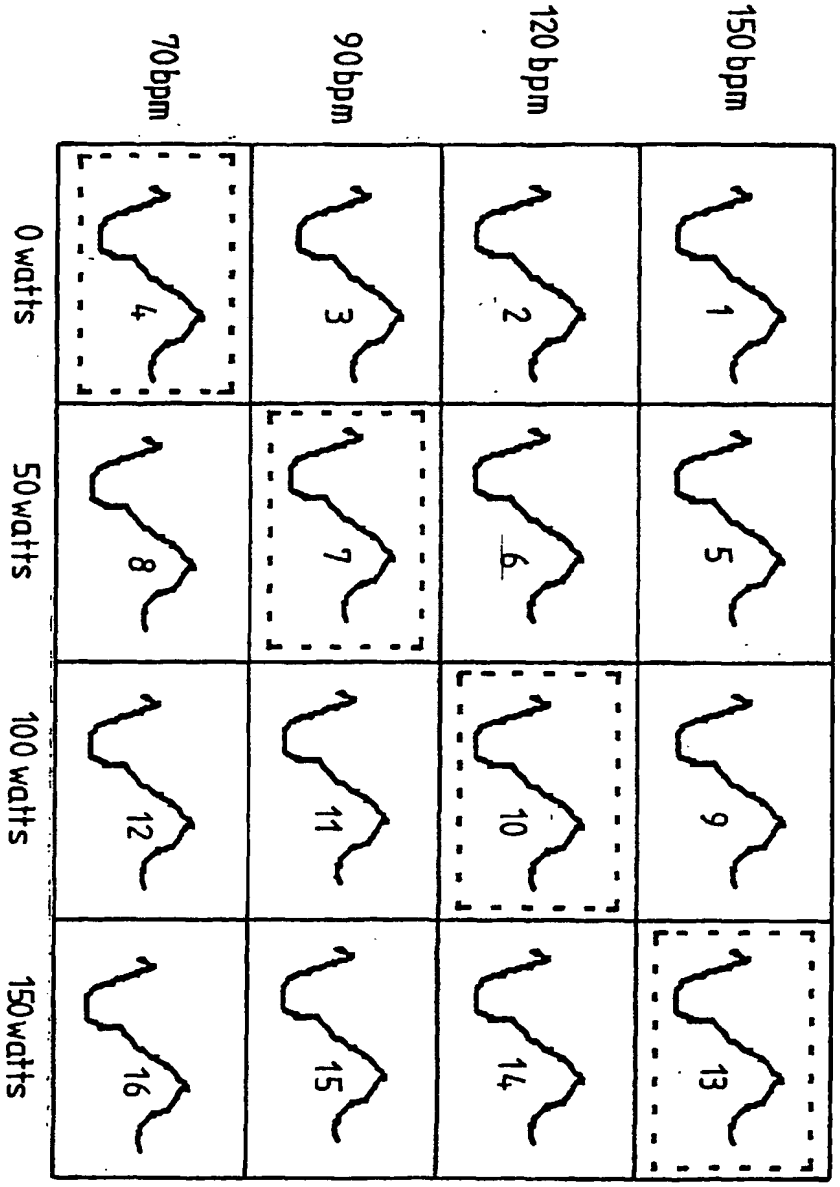

Fig. 4

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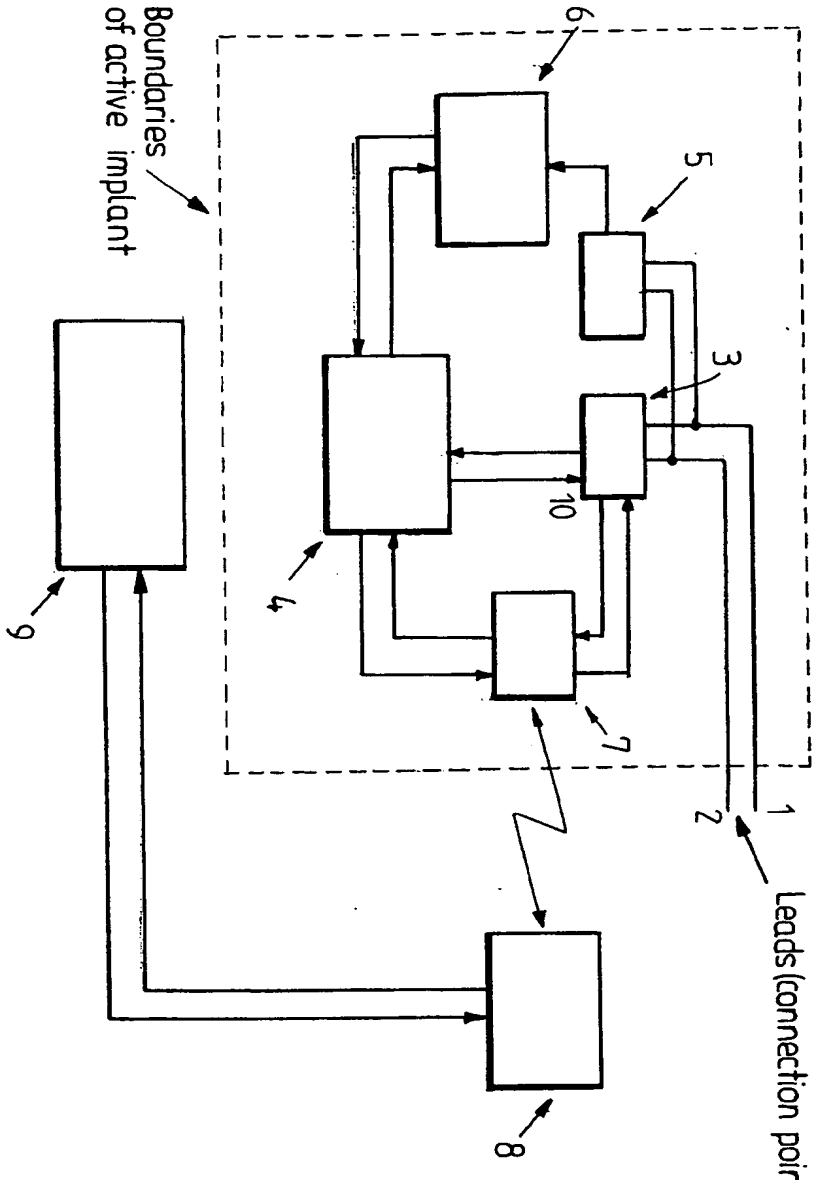

Fig.5

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Fig.6

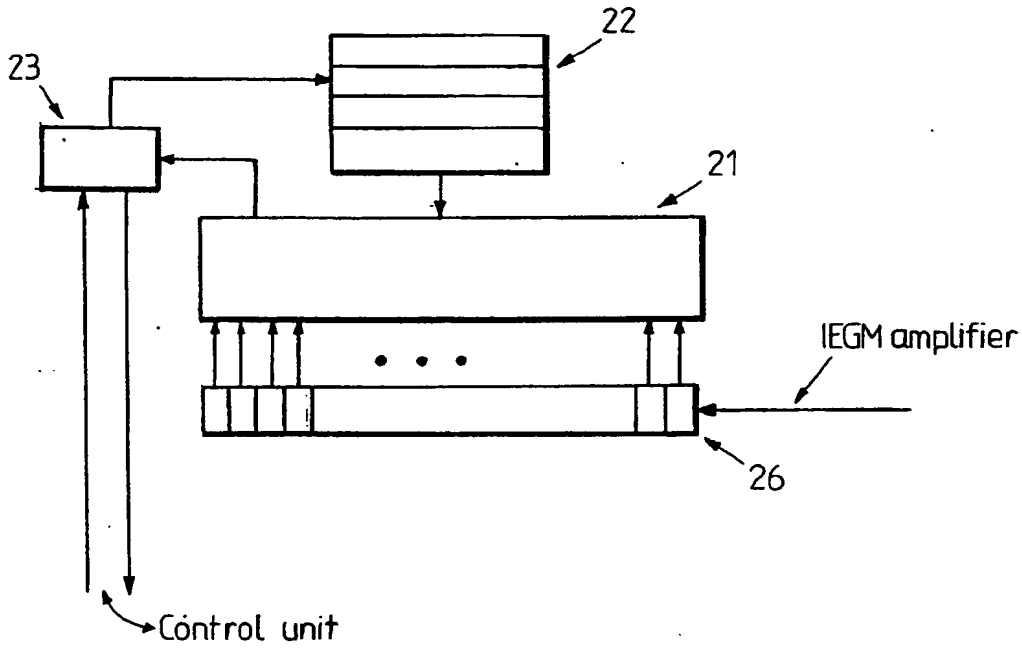
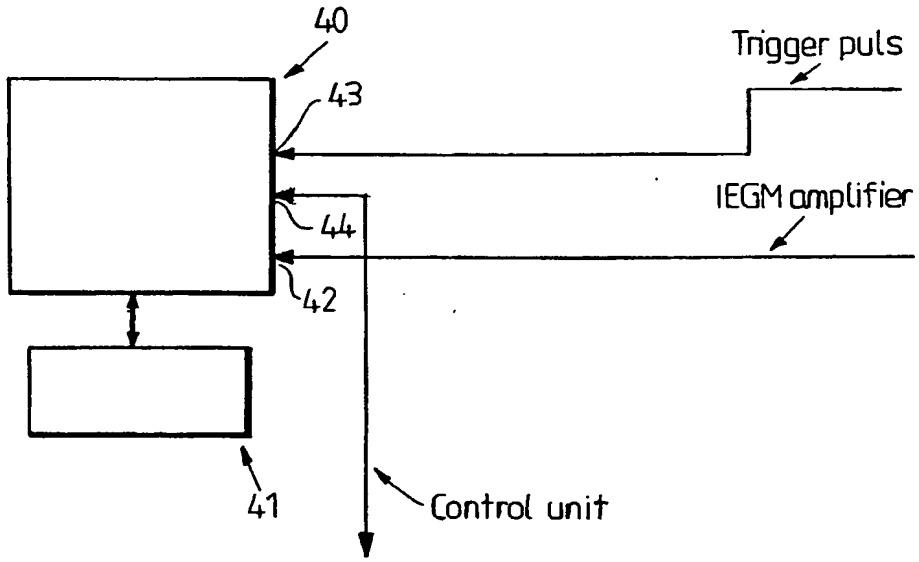


Fig.7



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European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 97 10 1787.6

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
A	US 5280792 A (PHILIP H.W. LEONG ET AL), 25 January 1994 (25.01.94) * abstract * --	1-5	A61N 1/365
A	EP 0465241 A2 (TELECTRONICS N.V.), 8 January 1992 (08.01.92) * abstract * --	1-5	
A	EP 0653224 A2 (TELECTRONICS N.V.), 17 May 1995 (17.05.95) * page 3, line 57 - page 4, line 14; page 11, line 19 - line 22 * --	1-5	
A	US 5000189 A (ROBERT D. THRONE ET AL), 19 March 1991 (19.03.91) * abstract * --	1-5	TECHNICAL FIELDS SEARCHED (Int. Cl.6) A61N
A	US 5312443 A (THEODORE P. ADAMS ET AL), 17 May 1994 (17.05.94) * column 10, line 19 - line 32 * -----	3	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	7 May 1997	THOMAS SKAGERSTEN

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
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T : theory or principle underlying the invention
E : e rlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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